



*American Academy of Dermatology*

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July 7, 1999

Food and Drug Administration  
Dockets Management Branch (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**ATTENTION:** *[Docket No. 98N-1170]*

**IN RE:** *Medical Devices; Sunlamp Products Performance Standard;  
Request for Comments and Information*

Dear Sir or Madam:

The American Academy of Dermatology [hereinafter referred to as the Academy] submits these comments in response to the notice of proposed rulemaking that was published in the *Federal Register*.

The American Academy of Dermatology firmly opposes indoor tanning and continues its longstanding support of a ban on the production and sale of indoor tanning equipment for non-medical purposes. The members of the Academy believe that the hazards of indoor tanning have been well documented from experimental sources, epidemiologic studies, and clinical observation. To this end, we have supported AMA Resolution 217-I-94, which calls for a ban on these devices.

Recently, the National Cancer Institute and the Centers for Disease Control and Prevention released their annual cancer report card. Once again, the report showed that the incidence of skin cancer had risen, while the incidence rate of nearly all other cancers had either stabilized or declined. Indeed, we predict that in 1999 incidence rate for the most dangerous form of skin cancer, malignant melanoma, is expected to increase by 6% over 1998 numbers.

A recent workshop convened by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Cancer Institute and the Food and Drug Administration (FDA) on the risks of ultraviolet (UV) radiation exposure and tanning noted that the tanning light sources contain significant amounts of both UVA and UVB radiation, and so mimic natural sun exposure. Many rigorous scientific articles, published in notable peer-reviewed journals, have linked the development of skin cancers to various wavelengths of UV radiation. Melanoma and nonmelanoma skin cancers have been linked to exposure to both UVA and UVB.

In addition to skin cancer, there are other adverse health effects caused by exposure to UV radiation, whether it is the sun or a tanning bed. There is strong evidence that UV exposure ages the skin and causes changes in the immune system. UV exposure can lead to disease induction such as

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pseudoporphyria, polymorphous light eruption and mid-dermal elastolysis. Persons already afflicted with lupus erythematosus, polymorphous light eruption, porphyria, rosacea, and other disorders can suffer significant side effects if exposed to UV radiation in a tanning bed. People taking photosensitizing medications may have severe reactions to UV exposure in a tanning bed. Also, our colleagues in the field of ophthalmology can attest to the damaging effects of tanning bed use to the human eye.

Therefore, the tanning industry's contention that their devices are "safer" than the sun or promote a "healthy" tan are without merit as most tanning equipment can now be rightly called solar simulators. A tan is not healthy, it is a complex, protective reaction by body to injury.

Tanning is not a health-promoting behavior, despite tanning industry claims to the contrary. Over the past few years, we have been bombarded by claims that tanning may prevent serious illness. Some of these claims border on the outrageous – including claims that tanning is a cancer-fighter and tanning lowers your risk for certain cancers, namely breast and colon cancer. Similar claims have also been made for tanning as a prevention strategy for osteoporosis. The tanning industry have published claims in their magazines that vitamin D production in the skin plays a role in warding off internal cancers and that tanning provides a better source of vitamin D, an essential nutrient, than dietary vitamin D. Vitamin D supplementation is an unproven strategy to reduce colon and breast cancer risk, and in any case, there is no evidence that vitamin D supplementation due to UVB exposure is superior to dietary supplementation. Furthermore, a six-year study, recently published in the *Journal of the American Academy of Dermatology*, found that regular sunscreen users, such as patients with xeroderma pigmentosum, were not vitamin D deficient.<sup>1</sup>

Until and unless the FDA bans the sale and use of tanning equipment for non-medical purposes, the Academy supports a more rigorous regulation of the indoor tanning industry. The Academy has many concerns about the adequacy of current regulation of this industry. We believe that inadequacy of both federal and state regulation of tanning equipment and parlors is putting many Americans at risk for skin cancer. We also have concerns that the regulation, as proposed, does not take into account the fact that many of these devices are used in ancillary facilities such as health clubs and in the home.

Although the Academy strongly urges the FDA to ban the production and sale of tanning equipment for non-medical purposes, we would like to comment on the revisions under consideration as outlined in the advanced notice:

1. We believe that the FDA should revise and update the current sunlamp product performance standards in light of recently published scientific studies linking exposure to UV radiation to skin cancer and other health effects. The Academy offers to the FDA its assistance in identifying important new research on the health dangers of tanning beds.
2. The Academy concurs with FDA that the maximum timer interval and recommended exposure schedule need to be strengthened. A recent investigative story published in a leading women's

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<sup>1</sup> "Normal vitamin D levels can be maintained despite rigorous photoprotection: six years' experience with xeroderma pigmentosum," Sollitto RB, Kraemer, KH, DiGiovanna, JJ, *Journal of the American Academy of Dermatology*, 1997 Dec; 37(6): 942-7.

magazine demonstrated the scant attention most tanning facilities pay to ensuring that their patrons do not over utilize tanning beds or using protective eyewear.

The Academy would support efforts by the FDA to require that no minor be permitted to use a tanning bed without written consent of a parent or guardian. The consent form should clearly inform parents that UV radiation is a known carcinogen and of the health risks of tanning devices and the potential impact that their use could have on the health of their children.

3. The Academy supports efforts by the FDA to strengthen its oversight of the manufacturing and modification of tanning devices. In addition to the recommendations noted in this section, the Academy recommends that tanning devices should be inspected regularly by competent local and state public health departments. The results of these inspections should be kept on file and available for public view. We believe that all tanning device operators should be required to receive adequate training to correctly operate the device, recognize injury or overexposure, accurately determine the skin type of individuals using their equipment, and to implement emergency procedures in the case of injury. Training regimens should also include important information on drug interactions and UV exposure. Tanning facility operators and their staff should be knowledgeable about all over-the-counter and prescription medications that can place the consumer at increased risk for erythema or other adverse health effects. Training should be repeated in the event that the manufacturer modifies equipment.
4. The Academy shares the FDA's concerns that too few tanning parlor patrons read the warning labels and are knowledgeable of the dangers of indoor tanning. The Academy is concerned that many tanning facilities do not post the warnings prominently.
5. The Academy is also greatly concerned that some tanning facilities are making health claims about their devices, including posting reports from tanning industry magazines that claim that tanning reduces your risk for skin cancer, internal cancers and osteoporosis. The Academy supports the development of a clear warning statement that must be posted prominently. Furthermore, the Academy urges the FDA to prohibit the display of materials that make unsubstantiated health claims on the purported benefits of tanning or the use of tanning beds. No person or facility should be allowed to advertise that their tanning devices promote a "safe tan," contain "no harmful rays," or similar wording concepts.
6. The Academy strongly supports improvements to the warning labeling. The Academy shares the FDA's concern that the warning label is overlong and not displayed prominently in tanning parlors. Warning labels should also be included in tanning device catalogues and other sales materials as well as included on devices sold for home use. Warning labels should also be affixed to all orders of replacement parts, including bulbs. Also, new patrons should be required to complete and sign a questionnaire that enumerates the potential hazards and consequences of exposure to UV radiation and the dangers of indoor tanning devices. This document should also contain information about the dangers of UV exposure when taking certain medications, the dangers of disease induction and exacerbation.
7. The Academy would note that the lack of a common grading/rating system puts physicians and scientists at a disadvantage when assessing the health risks of tanning devices. Many physicians

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are currently unaware that lamps used in tanning devices are solar simulators, generating both UVA and UVB radiation. The introduction of a simplified grading/rating system, however, should not obviate the need for periodic retraining of tanning parlor operators and their employees.

The Academy urges the FDA to adopt regulations that either ban the use of these devices outright or to significantly tighten federal regulation as a means of protecting public health. We hope that these comments are helpful to you. If the agency would like additional information on these or any other items, the Academy would be pleased to provide it.

With best wishes, I am most

Sincerely,  
President

A handwritten signature in black ink, appearing to read "Darrell Rigel". The signature is fluid and cursive, with the first name "Darrell" and last name "Rigel" clearly distinguishable.

Darrell Rigel, M.D.  
DR/cah